



remel

Niacin Reagent Strip

INTENDED USE

Remel Niacin Reagent Strip is recommended for use in the qualitative procedures for the differential identification of mycobacteria on the basis of niacin production.

SUMMARY AND EXPLANATION

Niacin or nicotinic acid plays a vital role in the oxidation-reduction reactions that occur during metabolic syntheses in all mycobacteria.¹ While all species produce nicotinic acid, *Mycobacterium tuberculosis* accumulates the largest amount in the medium on which it is growing and can therefore be detected on the basis of this evidence. In 1956, Konno devised the standard niacin test using chemical reagents.² This test was later modified by Runyon and associates.³ Kilburn, Kubica, and Young et al. demonstrated the niacin test using a paper strip method impregnated with test reagents.^{4,5}

PRINCIPLE

Niacin functions as a precursor in the biosynthesis of coenzymes. The accumulation of niacin in the culture medium is due to the lack of an enzyme that converts it to another metabolite in the coenzyme pathway.¹ Paper strips impregnated with potassium thiocyanate and chloramine T will release cyanogen chloride which in turn reacts with para-aminosalicylic acid to produce a yellow color in the presence of niacin.

REAGENTS (CLASSICAL FORMULA)*

Potassium Thiocyanate (CAS 333-20-0)	30.0	g
Chloramine T (CAS 127-65-1)	25.0	g
p-aminosalicylic Acid (CAS 6018-19-3)	5.0	g
Citric Acid Dihydrate (CAS 6132-04-3)	4.0	g
Ethyl Alcohol (CAS 64-17-5).....	50.0	ml
Demineralized Water (CAS 7732-18-5).....	150.0	ml

*Adjusted as required to meet performance standards.

PRECAUTIONS

This product is For *In Vitro* Diagnostic Use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original

container at 2-8°C until used. Allow product to come to room temperature before use. Do not incubate prior to use. Protect from light.

PRODUCT DETERIORATION

This product should not be used if (1) the color has changed from white, (2) the expiration date has passed, (3) the desiccant has changed from blue to white or pink, or (4) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE AND TRANSPORT

Specimens should be collected and handled following recommended guidelines.⁶

MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Quality control organisms, (6) Pipettes, (7) Sterile screw cap test tube, (8) Mycobacteriological safety equipment, (9) Sterile demineralized water.

PROCEDURE

Cultures grown on egg medium yield the most consistent results in the niacin test. When unusual circumstances necessitate the use of cultures grown on 7H10 or 7H11 Agar, use media supplemented with 0.1% potassium aspartate.¹ Before the niacin test is performed, cultures should be checked for purity by microscopy and should be 3-4 weeks old on egg medium; cultures should have sufficient growth of 50-100 colonies.

Niacin Test:

1. Add 1 ml of sterile, demineralized water to the surface of the egg-based medium on which the test organism is growing. Lay the tube horizontal, so that the fluid is in contact with the entire agar surface.
2. With the pipette used to add the water, puncture the surface of the slant several times, allowing the niacin in the medium to dissolve in the water.
3. Keep the tube tilted for up to 30 minutes at room temperature.
4. Transfer 0.6 ml of the demineralized water (which has become cloudy) to a sterile screw cap test tube.
5. Insert a Niacin Reagent Strip in the tube with the marked end UP.
6. Cap the tube tightly and incubate at room temperature for 15-20 minutes with occasional side-to-side shaking to mix the fluid with the reagent on the bottom of the strip. Do not invert the tube.
7. Observe the color of the liquid against a white background. Do not evaluate the color of the strip. Read the liquid extract within 30 minutes. After 30 minutes incubation, the color may fade.

- Before discarding the tubes, neutralize the strip with 10% sodium hydroxide, or an appropriate alkaline disinfectant to neutralize the cyanogen chloride. Dispose of by autoclaving.

- To prevent false-negative results, promptly reseal tubes after inserting the paper strip; if tubes are left unsealed, the gas produced by chemicals mixing on the strip may escape into the atmosphere.

INTERPRETATION

Positive Test - Yellow liquid
 Negative Test - Clear liquid

QUALITY CONTROL

All lot numbers of Niacin Reagent Strip have been tested using the following quality control organisms and have been found to be acceptable. Testing of a positive and negative control should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported.

CONTROL	INCUBATION	RESULTS
<i>Mycobacterium tuberculosis</i> ATCC® 25177	Aerobic, 15-20 min. @ RT	Positive
<i>Mycobacterium fortuitum</i> ATCC® 6841	Aerobic, 15-20 min. @ RT	Negative

LIMITATIONS

- The niacin test alone should not be used to identify *M. tuberculosis* because other species, including *M. simiae* and some strains of *M. chelonae*, consistently yield positive results.¹ Therefore, supportive tests of nitrate reduction and 68°C catalase testing are recommended to confirm the identity of *M. tuberculosis*.
- If cultures are niacin negative at 4 weeks, and if they have been handled aseptically, they may be reincubated for retesting at 6 weeks of age; otherwise, a fresh culture should be used.¹
- Since mycobacteria excrete niacin into the growth medium, cultures with confluent growth may give a false-negative niacin reaction because the extracting fluid cannot contact the culture medium. When this occurs, expose the underlying medium surface by scraping away or puncturing through some of the growth.




BIBLIOGRAPHY

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PACKAGING

REF 21090, Niacin Reagent Strip..... 25/Vial

Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)

ATCC® is a registered trademark of American Type Culture Collection. CAS (Chemical Abstracts Service Registry No.)

IFU 21090, Revised September 1, 2005 Printed in the U.S.A.

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